Core Centers for Musculoskeletal Disorders

Request For Applications (RFA) Number: RFA-AR-05-003

Part I Overview Information

Department of Health and Human Services

Participating Organizations
National Institutes of Health (NIH), (http://www.nih.gov/)

Components of Participating Organizations
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), (http://www.niams.nih.gov)

Announcement Type
This is a reissue of RFA-AR-03-004, released on November 21, 2002.

Catalog of Federal Domestic Assistance Number(s)
93.846

Key Dates
Release Date: November 2, 2004
Letters Of Intent Receipt Date(s): April 26, 2005
Application Receipt Dates(s): May 24, 2005
Peer Review Date(s): October/November 2005
Council Review Date(s): January 2006
Earliest Anticipated Start Date: March 1, 2006
Additional Information To Be Available Date: September 1, 2004:http://www.niams.nih.gov/rtac/funding/grants/sdrcwww.htm
Expiration Date: May 25, 2005

Due Dates for E.O. 12372
Not Applicable

Additional Overview Content

Executive Summary

- The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research core centers (P30s) for musculoskeletal disorders. The Core Centers for Musculoskeletal Disorders (CCMDs) will provide the resources for a number of established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in musculoskeletal disorders and to ensure greater productivity than from each of the separate projects.
- Three new and/or competing continuation grants are anticipated.
- Approximately $1.8 million in total costs (Direct costs plus Facilities and Administrative costs) may be awarded in support of this solicitation.
- Eligible organizations will generally be an organizational unit within an university-affiliated medical center and may include:
    - For profit or non-profit organizations
    - Public or private institutions , such as universities, colleges, hospitals, and laboratories
    - Units of State and local governments
    - Eligible agencies of the Federal government
    - Domestic institutions/organizations
- Foreign institutions are not eligible.
- Eligible principal investigators include Individuals with the skills, knowledge, and resources necessary to carry out the proposed research and to work with their institution to develop an application for support. Individuals from

underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

- Each institution can submit one application.
- General application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format.
- Application instructions and materials specific to the P30 grant mechanism are available at http://www.niams.nih.gov/rtac/funding/grants/centers_programs.htm#P30

For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088A concise description of the funding opportunity.

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Part II - Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Research in musculoskeletal disorders is at a stage where a number of areas are making broad advances that can be effectively fostered by research Core Centers. Examples of these areas include, but are not limited to:

o Regulation of skeletal growth and remodeling by systemic and local factors; diagnostic markers of skeletal remodeling; genetic basis of skeletal morphogenesis, growth, and disease.

o Mechanisms of bone repair and regeneration, including fracture healing; development of techniques for growth plate repair, reconstitution of large defects, and limb lengthening, including use of autografts and allografts, tissue engineering and distraction osteogenesis.

o Mechanisms of cartilage repair and regeneration, including chondroprogenitor cell biology, genetics, and biomechanical signaling; development of techniques for chondroprotection and repair of the articular surface, including gene therapy approaches and tissue engineering.

The investigators make the choice of research area upon which the CCMD would focus.

The CCMDs will provide support for:

1. Core resources and facilities to be used by investigators of individually supported research projects in order to enhance and coordinate their activities. This support may include personnel, equipment, supplies, services, and facilities;

2. Up to $100,000 yearly in direct costs for pilot and feasibility studies;

3. Program enrichment activities;

4. Administrative Core.

An Administrative Core should be proposed to coordinate the Center and administer the program enrichment activities. Two or more research cores must be proposed. A research core is a facility shared by two or more Center investigators that enables them to conduct their independently funded individual research projects more efficiently and/or more effectively. Cores generally fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service and training (e.g., molecular biology, biostatistics).

A pilot and feasibility study program provides modest research support ($20,000 - $50,000 direct costs yearly) for a limited time (1 to 3 years) to enable eligible investigators to explore the feasibility of a musculoskeletal-related concept and amass sufficient data to pursue it through other funding mechanisms. The initial set of pilot and feasibility studies must be part of the application. In addition, a plan for program management of the pilot and feasibility program will also be reviewed. The plan will include review of future pilot and feasibility applications during the tenure of the core center.

An investigator is eligible to be a principal investigator of a pilot and feasibility study only once every 5 years in a core center. Eligible investigators include:

1. New investigators without current or past NIH research project support (R01, P01, or current R55) as a principal investigator to engage in innovative research. However, a new investigator may have had funding through a pilot grant. New investigators

should be clearly independent and have a faculty appointment higher than that of postdoctoral fellow or research associate. Note that a new investigator is not just an investigator without previous R01, R29, P01 or R55 support as a principal investigator. A new investigator is someone who has not had extensive research experience and who has potential to be a productive investigator.

2. Established investigators with no previous work in research related to the focus of the Core Center who are willing to test the applicability of their expertise on a problem related to musculoskeletal disorders; and

3. Established investigators in the Core Center with a proposal for testing the feasibility of a new or innovative hypothesis that is related to the research focus of the Core Center, but represents a clear and distinct departure from the investigator's ongoing research interest.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the CCMD staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

Section II. Award Information

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1. Mechanism(s) of Support

This funding opportunity will use the P30 award mechanism(s). As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

This funding opportunity uses the just-in-time budget concepts. It also uses the non-modular budget format described in the PHS 398 application instructions (see http://grants.nih.gov/grants/funding/phs398/phs398.html). A detailed categorical budget for the "Initial Budget Period" and the "Entire Proposed Period of Support" is to be submitted with the application.

2. Funds Available

- The NIAMS expects to award approximately 1.8 million dollars in FY 2006 through this announcement;
- 3 awards are anticipated;
- Direct costs of up to $400,000 per year may be requested;
- March 1, 2006, is the earliest award date;
- The project period will be 5 years.

Although the financial plans of the IC(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. Fiscal and administrative costs are not included in the direct cost limitation, see NOT-OD-04-040.

Section III. Eligibility Information

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1. Eligible Applicants

1.A. Eligible Institutions

You may submit (an) application(s) if your organization has any of the following characteristics:

- For-profit organizations
- Non-profit organizations

- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Units of State government
- Units of local government
- Eligible agencies of the Federal government
- Domestic Institutions only

Any institution or consortium applying is expected to have an active program of excellence in both basic and clinical biomedical research in musculoskeletal disorders.

Foreign institutions are not eligible to apply.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

2. Cost Sharing

There are no requirements for cost sharing, matching, or cost participation for eligibility.

3. Other-Special Eligibility Criteria

Any institution or consortium with an active program of excellence in both basic and clinical biomedical research in musculoskeletal disorders may qualify for support through a Core Center. Only one application may be submitted per institution.

Section IV. Application and Submission Information

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1. Address to Request Application Information

The PHS 398 application instructions are available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email:GrantsInfo@nih.gov.

Telecommunications for the hearing impaired: TTY 301-451-0088.

2. Content and Form of Application Submission

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). Applications must have a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling (866) 705-5711 or through the web site at http://www.dnb.com/us/. The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

Application instructions and materials specific to the P30 grant mechanism are available at http://www.niams.nih.gov/rtac/funding/grants/sdrcwww.htm.

3. Submission Dates

Applications must be mailed on or before the receipt date described below (Section IV.3.A).

3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: April 26, 2005
Application Receipt Date(s): May 24, 2005
Peer Review Date: October/November 2005

Council Review Date: January 2006
Earliest Anticipated Start Date: March 1, 2006

3.A.1. Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document.

The letter of intent should be sent to:

Joan A. McGowan, Ph.D.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Musculoskeletal Diseases Branch Chief
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301)594-5055
FAX: 301-480-4543
Email:mcgowanj@mail.nih.gov

3.B. Sending an Application to the NIH

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and three signed photocopies in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710 (U.S. Postal Service Express or regular mail)
Bethesda, MD 20817 (for express/courier service; non-USPS service)

At the time of submission, two additional copies of the application and all copies of the appendix material must be sent to:

Joan A. McGowan, Ph.D.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Musculoskeletal Diseases Branch Chief
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301)594-5055
FAX: 301-480-4543
Email:mcgowanj@mail.nih.gov

Using the RFA Label: The RFA label available in the PHS 398 application instructions must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

3.C. Application Processing

Applications must be received **on or before the application receipt date** listed in the heading of this funding opportunity. If an

application is received after that date, it will be returned to the applicant without review. Applications will be evaluated for completeness by CSR.

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS . Incomplete and non-responsive applications will not be reviewed.

The NIH will not accept any application in response to this funding opportunity that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to a funding opportunity, it is to be prepared as a NEW application. That is, the application for the funding opportunity must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within eight (8) weeks.

4. Intergovernmental Review

This initiative is not subject to intergovernmental review.

5. Funding Restrictions

All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm (see also Section VI.3. Award Criteria).

6. Other Submission Requirements

Application instructions and materials specific to the P30 grant mechanism are available at http://www.niams.nih.gov/rtac/funding/grants/centers_programs.htm#P30.

Plan for Sharing Research Data

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation to be provided, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement. References to data sharing may also be appropriate in other sections of the application.

Applicants requesting more than $500,000 in direct costs in any year of the proposed research must include a plan for sharing research data in their application. The funding organization will be responsible for monitoring the data sharing policy (http://grants.nih.gov/grants/policy/data_sharing).

The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm and http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm#_Toc54600131). Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590,

http://grants.nih.gov/grants/funding/2590/2590.htm). See Section VI.3. Award Criteria.

Unique research resources may be generated in a core of the proposed CCMD. If this is anticipated, include a resource sharing plan in the core proposal.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process.

2. Review and Selection Process

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS . Incomplete applications will not be reviewed.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NIAMS in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Receive a written critique.
- Receive a second level of review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

3. Merit Review Criteria

The goals of NIH supported research are to advance our understanding of biological systems, to improve the control of disease, and to enhance health. In their written critiques, reviewers will be asked to comment on each of the following criteria in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. Approach. Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. Investigators. Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

3.A. Additional Review Criteria:

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

CCMD Leadership:

Do the Director and Associate Director have the leadership and research qualifications to lead a Center? Does the leadership team (Director, Associate Director, and executive committee) have the collective expertise to assure focused development and implementation of high quality and meaningful clinical research projects?

Research Base:

Is there a substantial productive and funded research base? Is the research base sufficiently broad to foster new research? Will the proposed cores enhance the research base? Is there a definition of who will be a Center investigator and what this designation might mean?

Institutional Base:

Is there evidence of a supportive institutional environment for the proposed Core Center? Will the Core Center add an important research element to the institutional environment? Does the proposed Core Center utilize available resources well? Is there support and commitment from the institutional authorities?

Applications Seeking Competitive Renewal:

Does the progress report reflect significant accomplishments that were derived from the Core Center, especially as reflected in new grants and publications?

Pilot and Feasibility Program Management:

Is the management proposed appropriate for reviewing and mentoring investigators in pilot and feasibility program?

Administrative Unit:

1. Significance: Does the proposed Core Center document coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring? Is there a plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators, core leaders and an executive committee? Are there plans for outside review and input?

2. Approach: Is the management proposed appropriate for 1) fiscal administration, procurement, property and personnel management, planning, budgeting, etc.; 2) Are the Core Center budgets appropriate for the proposed and approved work to be done in core facilities, for pilot and feasibility studies, and for enrichment in relation to the total Core Center program?

3. Innovation: Is there a plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators and for an enrichment program that provides outside review and input?

4. Investigators: Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the Core Center Director and Associate Director for the effective management of the Core Center program?

5. Environment: Have institutional lines of authority and sanction been documented for the Core Center?

Research Cores:

1. Significance: Will the core have utility to the Core Center research base (minimum: two independently funded investigators)?

2. Approach: Is the quality of services high? Are there procedures for quality control? Is the core cost effective? How is cost reimbursement proposed?

3. Innovation: Will the core likely promote interdisciplinary research? Are unique services offered?

4. Investigator: Are the personnel appropriate?

5. Environment: Are the facilities and equipment adequate? Is there institutional commitment to the core?

Pilot and Feasibility Projects:

1. Significance: Will the proposed work likely yield meaningful preliminary data leading to a research proposal?

2. Approach: Are the experimental approaches adequate?

3. Innovation: Is the research topic one that promotes innovative new research related to the Core Center?

4. Investigator: Does the investigator meet one of the criteria for P&F investigators? (If not, the project should not be considered further.)

5. Environment: Is the project appropriate to the research base of the Core Center? Does one or more of the cores offer needed materials/assistance?

After the review of the individual components of the application, an application may be judged non-competitive and not scored, or may be discussed and assigned an overall priority score. This score will reflect not only the individual quality of the cores, administration and pilot projects, but also the quality of the research base and how the proposed Core Center will enhance the research base. The overall score may be higher or lower than the average of the descriptors based on the assessment of whether the whole is greater than the sum of its parts.

The following elements will be evaluated for the overall priority score:

1. The scientific excellence of the Core Center's research base as well as the relevance and interrelation of these separately funded research projects to the central themes of the Core Center and the likelihood for meaningful collaboration among Core Center investigators. Existence of a base of established independently supported biomedical research of high quality is a prerequisite for establishment of a Core Center.

2. The application must convey how the proposed Core Center will enhance significantly the established research base of the host institution. In a competing continuation application, the application should document an impact of the Core Center. This includes the qualifications, experience, and commitment of the Core Center investigators and their willingness to interact with each other. This also includes efficient and effective use and/or planned use of enrichment funds including the contribution of these activities in enhancing the realization of the Core Center concept.

3. The appropriateness, quality and relevance of the proposed cores, and the modes of operation, facilities, and potential for contribution to ongoing research.

4. The proposed management of the pilot and feasibility program and the scientific merit of the pilot and feasibility projects for which funds are requested from the Core Center grant. The effectiveness of the proposed program will serve as a basis for recommendations concerning the level at which pilot and feasibility studies will be supported throughout the project period.

5. The overall environment for a Core Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Core Center, and the institution's partnership with the Core Center, and the institutional commitment to individuals responsible for conducting essential Core Center functions. This also includes the academic environment and resources in which the activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Care and Use of Vertebrate Animals in Research: If vertebrate animals are to be used in the project, the five items described under Section F of the PHS Form 398 research grant application instructions will be assessed.

3.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

3.C. Sharing Research Data

1. **Data Sharing Plan:** The reasonableness of the data sharing plan or the rationale for not sharing research data may be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score. The funding organization will be responsible for monitoring the data sharing policy. http://grants.nih.gov/grants/policy/data_sharing.

3.D. Sharing Research Resources

NIH policy requires that grant awardee recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (See the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps/part_ii_5.htm#availofrr and http://ott.od.nih.gov/newpages/rtguide_final.html). Investigators responding to this funding opportunity should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible. Unique research resources may be generated in a core of the proposed CCMD. If this is anticipated, include a resource sharing plan in the core proposal.

The adequacy of the resources sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. Program staff may negotiate modifications of the data and resource sharing plans with the awardee before recommending funding of an application. The final version of the data and resource sharing plans negotiated by both will become a condition of the award of the grant. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590). See Section VI.3. Award Criteria.

Section VI. Award Administration Information

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1. Award Notices

After the peer review of the application is completed, the Principal Investigator will also receive a written critique called a Summary Statement.

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant. For details, applicants may refer to the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part4.htm).

A formal notification in the form of a Notice of Grant Award (NGA) will be provided to the applicant organization. The NGA signed by the grants management officer is the authorizing document.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NGA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. Once all administrative and programmatic issues have been resolved, the Notice of Grant Award will be generated via e-mail notification from the awarding component, NIAMS, to the grantee business official (designated in item 14 on the application Face Page). If a grantee is not e-mail enabled, a hard copy of the Notice of Grant Award will be mailed to the business official.

2. Administrative Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the notice of grant award. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part4.htm) and Part II Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_part9.htm).

3. Award Criteria

The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review
- Availability of funds
- Relevance of program priorities

4. Reporting

Awardees will be required to submit the PHS Non-Competing Grant Progress Report, Form 2590 annually (http://grants.nih.gov/grants/funding/2590/2590.htm) and financial statements as required in the NIH Grants Policy Statement. New pilot and feasibility studies must be included in the non-competing grant progress report.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. Scientific/Research Contacts:

Joan A. McGowan, Ph.D.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Musculoskeletal Diseases Branch Chief
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301)594-5055
FAX: 301-480-4543
Email:mcgowanj@mail.nih.gov

2. Peer Review Contacts:

Yan Wang, Ph.D.
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Acting Chief, Review Branch
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301) 594-4952
FAX: (301) 402-2406
Email:wangy1@mail.nih.gov

3. Financial or Grants Management Contacts:

Michael Morse
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Extramural Program
Deputy Chief, Grants Management Branch
6701 Democracy Boulevard, Suite 800, MSC 4872
Bethesda, MD 20892-4872
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email:morsem@mail.nih.gov

Section VIII. Other Information

Required Federal Citations

Use of Animals in Research:
Recipients of PHS support for activated involving live, vertebrate animals must comply with PHS Policy on Humane Care and

Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf) as mandated by the Health Research Extension Act of 1985 (http://grants.nih.gov/grants/olaw/references/hrea1985.htm), and the USDA Animal Welfare Regulations (http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) as applicable.

Human Subjects Protection:
Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).

Data and Safety Monitoring Plan:
Data and safety monitoring is required for all types of clinical trials, including physiologic toxicity and dose-finding studies (phase I); efficacy studies (Phase II); efficacy, effectiveness and comparative trials (Phase III). Monitoring should be commensurate with risk. The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risks to the participants (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

Sharing Research Data:
Investigators submitting an NIH application seeking $500,000 or more in direct costs in any single year are expected to include a plan for data sharing or state why this is not possible (http://grants.nih.gov/grants/policy/data_sharing).

Investigators should seek guidance from their institutions, on issues related to institutional policies and local IRB rules, as well as local, State and Federal laws and regulations, including the Privacy Rule. Reviewers will consider the data sharing plan but will not factor the plan into the determination of the scientific merit or the priority score.

Sharing of Model Organisms:
NIH is committed to support efforts that encourage sharing of important research resources including the sharing of model organisms for biomedical research (see http://grants.nih.gov/grants/policy/model_organism/index.htm). At the same time the NIH recognizes the rights of grantees and contractors to elect and retain title to subject inventions developed with Federal funding pursuant to the Bayh Dole Act (see the NIH Grants Policy Statement http://grants.nih.gov/grants/policy/nihgps_2003/index.htm). All investigators submitting an NIH application or contract proposal, beginning with the October 1, 2004 receipt date, are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible. This will permit other researchers to benefit from the resources developed with public funding. The inclusion of a model organism sharing plan is not subject to a cost threshold in any year and is expected to be included in all applications where the development of model organisms is anticipated.

Inclusion of Women And Minorities in Clinical Research:
It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43). All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm . The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

Inclusion of Children as Participants in Clinical Research:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all clinical research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects (http://grants.nih.gov/grants/funding/children/children.htm).

Required Education on the Protection of Human Subject Participants:
NIH policy requires education on the protection of human subject participants for all investigators submitting NIH applications for research involving human subjects and individuals designated as key personnel. The policy is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

Human Embryonic Stem Cells (hESC):
Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (http://escr.nih.gov/). It is the responsibility of the applicant to provide in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

Public Access to Research Data through the Freedom of Information Act:
The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm. Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Standards for Privacy of Individually Identifiable Health Information:
The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule", on August 14, 2002 . The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs in NIH Grant Applications or Appendices:
All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

Healthy People 2010:
The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

Authority and Regulations:
This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Loan Repayment Programs:
NIH encourages applications for educational loan repayment from qualified health professionals who have made a commitment to pursue a research career involving clinical, pediatric, contraception, infertility, and health disparities related areas. The LRP is an important component of NIH's efforts to recruit and retain the next generation of researchers by providing the means for developing a research career unfettered by the burden of student loan debt. Note that an NIH grant is not required for eligibility and concurrent career award and LRP applications are encouraged. The periods of career award and LRP award may overlap providing the LRP recipient with the required commitment of time and effort, as LRP awardees must commit at least 50% of their

time (at least 20 hours per week based on a 40 hour week) for two years to the research. For further information, please see:http://www.lrp.nih.gov/.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

Department of Health
and Human Services

National Institutes of Health (NIH)
9000 Rockville Pike
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